

Attorney Dkt. No. M233 1030.1

Remarks

Applicants wish to thank the Examiner for the helpful interview held on July 16, 2007. Although agreement was not reached, Applicants agreed to amend the claims to specify that the calcium phosphate is dibasic calcium phosphate dihydrate, and to present information on the differences between calcium phosphate and dibasic calcium phosphate dehydrate. In the instant amendment, Applicants have amended the claims as discussed with the Examiner.

Rejections under 35 U.S.C. §112, Second Paragraph

Claim 56 was rejected under 35 U.S.C. §112, second paragraph, as indefinite on the basis that the claim depended on previously cancelled Claim 1. Claim 56 has been amended to depend from Claim 43, as suggested by the Examiner.

Rejections under 35 U.S.C. §103 (a)

Claims 43-53 and 55 remain rejected under 35 U.S.C. §103 as purportedly being obvious over U.S. Patent No. 5,958,458 to Norling et al. ("Norling"). Claims 56 and 57 were rejected under 35 U.S.C. §103 as purportedly being obvious over Norling in view of U.S. Patent Application Publication No. 2003/0050228 to Ekwuribe et al. ("Ekwuribe"). These rejections are respectfully traversed if applied to the amended claims.

Emcompress® (dibasic calcium phosphate dihydrate) is a direct compression tablet binder excipient. Its particles are of a size, shape, and density to maximize flow in high-speed tablet production and to reduce tablet weight variation. As such, it is different from ordinary calcium phosphate. Unlike ordinary calcium phosphate, Emcompress® is directly compressible, is granular, and has significantly different particle size, density and flow characteristics.

In the instant application, the ability to form a tablet (for which Emcompress® is commonly used) is not the only criteria wherein the material is different from ordinary calcium phosphate. In addition to tableting properties, the particles need to be able to accept a coating of insulin before being tableted.

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Ordinary calcium phosphate has significantly less flow and propensity to accept a coat than Enecompress[®], and is therefore less useful in preparing the instantly claimed pharmaceutical formulations. Further, Applicants are unaware of any prior coating of Enecompress[®] before the particles are tableted.

Applicants respectfully submit that it would not have been obvious, based solely on the known utility of this material to form tablets when blended with a pharmaceutically active agent, that the particles could be coated with insulin and retain their superior ability to form tablets. Upon request, Applicants will submit a Declaration regarding the superior properties of Enecompress[®] dibasic calcium phosphate dihydrate in forming the claimed pharmaceutical formulations, relative to calcium phosphate.

Further, with respect to Claims 56 and 57, it would not have been obvious in view of Norling to use the HIM-2 version of insulin of Ekwuribe. If Norling's formulation was sufficient to administer insulin orally, without chemically modifying the insulin, then it would not have been necessary to prepare a specifically modified form of insulin, specially adapted for oral administration. This additional modification requires significant additional effort and expense. Applicants submit that it would not be obvious to have done so, due to a lack of motivation to do so. That is, there is no motivation to use exotic materials, such as those described in the secondary reference (Ekwuribe), when the primary reference (Norling) teaches that ordinary, unmodified materials will suffice.

For at least these reasons, Applicants submit that the claims as amended are non-obvious.

Conclusion

Applicants respectfully submit that the claims as amended are in condition for allowance, and acknowledgment of same is earnestly solicited. If the Examiner disagrees, and believes that a Declaration should be submitted articulating the beneficial properties that the dibasic calcium phosphate dihydrate has in contrast to ordinary calcium phosphate, Applicants will consider submitting such a Declaration.

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Respectfully submitted,

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